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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/060,588	01/30/2002	Shoky Gen	F-7296	8285

28107 7590 03/04/2004  
JORDAN AND HAMBURG LLP  
122 EAST 42ND STREET  
SUITE 4000  
NEW YORK, NY 10168

EXAMINER

AZPURU, CARLOS A

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 03/04/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/060,588	<b>Applicant(s)</b> GEN, SHOKYU	
	<b>Examiner</b> Carlos A. Azpuru	<b>Art Unit</b> 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 10 December 2003.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 6-10,12,15-23 and 28-33 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 6-9,12,15-22,25 and 30-33 is/are rejected.
- 7) ☒ Claim(s) 10,23,28 and 29 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

Receipt is acknowledged of the amendment and remarks filed 12/10/2003.

The claim objection is withdrawn in response to applicant's amendment of the claims.

The following rejection is maintained in this action:

#### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 6-9, 15-22, and 30-33 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Peterson et al.

Peterson et al disclose a pressure sensitive adhesive composition comprising a poly(amino acid), an extraneous protein and a free radical scavenger (antioxidant) (see col. 6, lines 18-30). The free radical scavenger may be gallate, BHA, or ascorbic acid (Vitamin C). The poly(amino acid) may be complexed with organic or inorganic fillers including apatite (see col. 5, lines 28-31). Sterilization of the composition can occur either by radiation at a dose of 1 to about 3 mRad (col. 6, lines 23-24) or at a low

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temperature as taught at col. 6, lines 33-34. The drop in molecular weight of the claimed polymers subsequent to the exposure to heat or radiation is an inherent property of the biodegradable polymers claimed since the same polymers are disclosed for use on preparation. Formation of the polymer composition occurs at a temperature of from about 4 to about 60 C. The instant claims are clearly anticipated by Peterson et al.

### ***Response to Arguments***

Applicant's arguments filed 12/10/03 have been fully considered but they are not persuasive.

Applicant argues that the free radical scavengers have been amended around those presently in the claims. However, review of the reference at the cited column and lines shows that the reference contains both gallate (gallic acids) and tocopherol (Vitamin E). Further, the reference goes on to say that any safe free radical scavenger may be used in the composition, and is not limited to those explicitly recited.

Applicant further argues that claims directed to both heat treatment and sterilization through radiation should be allowed over the reference. However, the reference teaches that a low temperature heating is maintained during sterilization. Further it should be noted that applicants appear to be using the heating used in the molding process as their heat treatment. As such, the reference also teaches this use of heat in the formation of the claimed polymer system. The rejection of the claims under 35 USC 102(b) is hereby maintained.

The following rejections are newly cited in response to applicant's amendments:

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 12 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Peterson et al.

Peterson et al disclose a pressure sensitive adhesive composition comprising a poly(amino acid), an extraneous protein and a free radical scavenger (antioxidant) (see col. 6, lines 18-30). The free radical scavenger may be gallate, BHA, or ascorbic acid (Vitamin C). The poly(amino acid) may be complexed with organic or inorganic fillers including apatite (see col. 5, lines 28-31). Sterilization of the composition can occur either by radiation at a dose of 1 to about 3 mRad (col. 6, lines 23-24) or at a low temperature as taught at col. 6, lines 33-34. The drop in molecular weight of the claimed polymers subsequent to the exposure to heat or radiation is an inherent property of the

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biodegradable polymers claimed since the same polymers are disclosed for use on preparation. Formation of the polymer composition occurs at a temperature of from about 4 to about 60 C. The reference differs in that the specific free radical scavenger of the claims is not recited.

Peterson et al does however include a general teaching that any free radical scavenger may be used in the instant composition and method. Therefore, those of ordinary skill would have expected similar therapeutic results from the use of any free radical scavenger given the teachings of Peterson et al. The instant claims would therefore have been obvious given the teachings of Peterson et al.

Claims 10, 23, 28, and 29 are objected to as dependent upon a rejected base claim.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

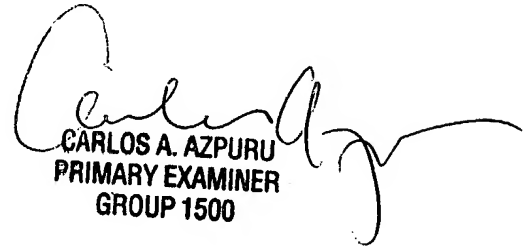
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carlos A. Azpuru whose telephone number is (571) 272-0602. The examiner can normally be reached on Tu-Fri, 6:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on (571) 272-0588. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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